AMENDMENTS TO THE CLAIMS

Please amend claim 28 without prejudice or disclaimer. The following listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A process for producing a blood plasma-derived IαIp composition comprising a mixture of inter-alpha inhibitor protein (IαI) and pre-alpha protein (PαI), wherein the IαI and the PαI are present in said mixture in a physiological proportion, the process comprising:

isolating from blood plasma a plasma fraction containing IαI and PαI, wherein the IαI and PαI are present in a physiological proportion; and

purifying the plasma fraction to obtain an IαIp composition with a purity of IαIp ranging from about 85% to about 100% pure.

2. (Previously presented) The process of claim 1, wherein the isolating comprises solid phase extraction or chromatographing blood plasma.

3-9. (Canceled)

10. (Previously presented) The process of claim 1, wherein the plasma fraction comprises a side fraction obtained from the purification of clotting factor IX or from the purification of a prothrombin complex concentrate.

11. (Canceled)

12. (Previously presented) The process of claim 1, wherein the plasma fraction is isolated as a cryosupernatant resulting from cryoprecipitation of blood plasma.

13. (Previously presented) The process of claim 1, wherein the plasma fraction is cryo-poor plasma.

14. (Previously presented) The process of claim 1, wherein the plasma fraction is human, primate, bovine, porcine, feline, or canine.

15. (Previously presented) The process of claim 1, further comprising obtaining blood, obtaining blood plasma, obtaining a side fraction obtained from the purification of clotting factor IX, obtaining a side fraction from the purification of a prothrombin complex concentrate, obtaining a cryosupernatant resulting from cryoprecipitation of blood plasma or obtaining cryo-poor plasma.

16-20. (Canceled)

21. (Previously presented) The process of claim 1, wherein the purifying is by hydroxylapatite chromatography, affinity chromatography or a combination thereof.

22-24. (Canceled)

25. (Previously presented) The process of claim 1, wherein the IαI and PαI present in the plasma fraction have an apparent molecular weight of between about 60,000 to about 280,000 kDa.

26. (Canceled)

27. (Previously presented) The process of claim 1, further comprising: further purifying the plasma fraction; virus inactivating the plasma fraction and/or the purified IαIp; the addition of stabilizers; comprising pasteurization of the purified IαIp; or anion-exchange chromatography of the purified IαIp.

28. (Currently amended) The process of claim 27, wherein the further purifying the plasma fraction is by passing through heparin affinity column and collecting the flow through (unbound) fraction; the virus inactivating is by a solvent/detergent treatment or thermal inactivation; and the anion-exchange

chromatography of the purified IαIp is diethylaminoethyl (DEAE) Sepharose.

29-30. (Canceled)

31. (Previously presented) The process of claim 28, wherein the thermal inactivation comprises pasteurization at a temperature of between about 55 to about 65℃. or dry heat at 70 to 120℃.

32-39. (Canceled)

40. (Original) A composition of IαIp comprising a mixture of inter-alpha inhibitor protein (IαI) and pre-alpha protein (PαI), wherein the IαI and the PαI are present in said mixture in a physiological proportion ranging from about 85% to about 100% pure.

41. (Original) The composition of claim 40, wherein the IαIp comprises between about 60% to about 80% IαI and between about 40% to about 20% PαI.

42. (Original) The composition of claim 40, wherein the physiological proportion is the ratio of IαI to PαI that appears naturally in human plasma.

43-44. (Canceled)

45. (Original) The composition of claim 40, further comprising a stabilizing agent.

46. (Original) The composition of claim 45, wherein the stabilizing agent is albumin, polyethylene glycol, alpha,alpha-trehalose, amino acids, salts, glycerol, omega-amino acids, sugar, or combinations thereof.

47. (Previously presented) A composition of IαIp comprising a mixture of

inter-alpha inhibitor protein (IαI) and pre-alpha protein (PαI), wherein the IαI and the PαI are present in said mixture in a physiological proportion and: have a high trypsin inhibitory specific activity; have a half life of greater than one hour; comprise a light chain of inter-alpha inhibitor protein associated with at least one of three heavy chains H1, H2 and H3; or comprise a light chain of inter-alpha inhibitor protein associated with at least one of three heavy chains H1, H2, H3 and H4.

48. (Previously presented) The composition of claim 47, wherein the the trypsin inhibitory specific activity is between about 1000 to about 2000 IU/mg.

49-55. (Canceled)

56. (Previously presented) The composition of claim 47, wherein the IαIp composition has a half life of at least 5 hours.

57. (Previously presented) The composition of claim 47, wherein the IαIp composition has a half life of at least 10 hours.

58-76. (Canceled)

77. (Previously presented) A composition of IαIp comprising a mixture of inter-alpha inhibitor protein (IαI) and pre-alpha protein (PαI), wherein the IαI and the PαI are present in said mixture in a physiological proportion, said composition having been prepared by the process according to claim 1.

78. (Previously presented) The composition of claim 40, further comprising an additional therapeutic agent.

79. (Original) The composition of claim 78, wherein the additional therapeutic agent is an anticancer agent, an anti-inflammatory agent, an anti-coagulant or an immunomodulator.

80. (Previously presented) A pharmaceutical composition comprising a therapeutically effective amount of the composition of claim 40, and a pharmaceutically acceptable carrier.

81. (Previously presented) A method of treating an inflammation related disorder, cancer, or an infectious disease in a subject comprising, administering a therapeutically effective amount of the composition of claim 40 or 77.

82. (Original) The method of claim 81, wherein the IαIp is isolated from a subject.

83. (Original) The method of claim 82, wherein the subject is a human, cow, pig, goat, or primate.

84. (Original) The method of claim 81, wherein the IαIp is administered as a tablet, capsule, or injectables.

85. (Original) The method of claim 81, wherein the IαIp is at least 85% pure.

86. (Original) The method of claim 81, wherein the IαIp is between about 85% to about 100% pure.

87. (Canceled)

88. (Withdrawn) A method of treating a subject for acute inflammatory disease, sepsis, severe shock, septic shock, rheumatoid arthritis, cancer, cancer metastasis, infectious disease, or preterm labor, comprising:

(a) determining the pre-treatment level of one or more of the following levels in a subject:

(i) the level of IαI;

(ii) the level of PαI;

(iii) the level of IαIp;

(iv) the level of H3;

(v) the level of H4;

(vi) the level of H1;

(vii) the level of H2; and

(viii) the level of LC; and

(b) administering a therapeutically effective amount of the composition of claim 40 or 77 to the subject.

89-95. (Canceled)

96. (Withdrawn) A method for predicting a response to an IαIp therapy, comprising:

assaying a sample obtained from a subject to detect the level of one or more of the following:

(i) IαI;

(ii) PαI;

(iii) IαIp;

(iv) H3;

(v) H4;

(vi) H1;

(vii) H2; and

(viii) LC; wherein the detected levels identifies a subject that may respond favorable to IαIp therapy.

97. (Canceled)

98. (Withdrawn) A method of monitoring the progress of a subject being treated with an IαIp therapy, comprising:

(a) determining the pre-treatment level of one or more of the following levels, in a subject:

(i) the level of IαI;

(ii) the level of PαI;

(iii) the level of IαIp;

(iv) the level of H3;

(v) the level of H4;

(vi) the level of H1;

(vii) the level of H2; and

(viii) the level of LC;

(b) administering a therapeutically effective amount of the composition of claim 40 or 77 to the subject; and

(c) determining the level of one or more of the levels in the subject after an initial period of treatment with the composition,

wherein an increase of the level in the subject following treatment with the composition indicates that the subject is likely to have a favorable clinical response to treatment with IαIp.

99. (Withdrawn) A kit for IαIp therapy comprising one or more of the following:

(i) IαI;

(ii) PαI;

(iii) IαIp;

(iv) H3;

(v) H4;

(vi) H1;

(vii) H2; and

(viii) LC; and

instructions for therapeutic use.

100. (Canceled)

101. (Previously presented) A kit comprising a composition according to claim 40 or 77 and instructions for therapeutic use.